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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/774,928

02/09/2004

Jose A. O'Daly

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EXAMINER

GRASER, JENNIFER E

ART UNIT

PAPER NUMBER

1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/06/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/774,928

Applicant(s)

O'DALY, JOSE A.

Examiner

Jennifer E. Graser

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1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 2 and 21-38 is/are pending in the application.
- 4a) Of the above claim(s) 27, 29, 30, 32, 33, 35, 36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 21-26, 28, 31, 34 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Acknowledgment and entry of the Amendment submitted on 12/18/06 is made. Claims 1, 2 and 21-38 are currently pending. Claims 27, 29, 30, 32-33, 35-36, and 38 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 1, 2, 21-26, 28, 31, 34, and 37 are currently under examination.

#### ***Claim Rejections - 35 USC § 112-2<sup>nd</sup> paragraph***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 2, 21, 22, 23-26, 28, 31, 34, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to the phrase "*interferes* with at least one of the following interactions: a CLA and E-selectin interaction ...". It is unclear what is meant by the term 'interferes'. Is this 'an inhibition', "an immunostimulation", etc.? The metes and bounds of the phrase cannot be understood. Applicants have argued that the "interference results in an inhibition of T cell rolling". They argue that this need no be an immunosuppression or elimination of T cells, but rather one can provide an immunostimulator. This has been fully and carefully considered but is not deemed persuasive in overcoming the rejection. The compound and/or how it interferes is critical to the claimed invention. While the specification can be used to provide definitive

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support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed.

Claims 21, 22, 23-26, 28, 31, 34, and 37 are vague and confusing because it is unclear whether the claimed methods intend to use isolated protein and/or mixtures of three isolated proteins or if the agent is a purified protein extract as claimed in parent application 09/809,003 (now US Patent No. 6,673,351). Claim 21 does not adequately define the agent which is to be used in the claimed methods if the agent is intended to be a purified protein extract because the extract can continually change depending on the method used to isolate it from the killed amastigote cells. Therefore, the metes and bounds of the invention cannot be understood. The extract should be defined as recited in claim 1 of US Patent No. 6,673,351. Applicants argue that while the claims of US Patent No. 6,673,351 are directed to immunotherapeutic agents that abate psoriasis, the present claims are directed to methods of inhibiting T-cell rolling using a compound that interferes with a mechanism of action crucial to T-cell rolling. They argue that any compound that inhibits T-cell rolling may be used in the methods and, therefore, the claim need not be limited to a specific compound. This has been fully and carefully considered but is not deemed persuasive. It is unclear what structure is defined by the function "inhibits T-cell rolling". While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and

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complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. The compounds appear to be critical to the practice of the invention.

***Claim Rejections - 35 USC § 112-Scope of Enablement***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 21, 22, 23-26, 28, 31, 34, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "A method for the abatement of clinical symptoms of psoriasis comprising administering a an immunotherapeutic agent comprising a purified protein extract wherein said purified extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa", does not reasonably provide enablement for "a method for selectively inhibiting T-cell rolling in a human host, the method comprising the step of administering **[any]** compound

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that interferes with at least one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The claimed method allows for use of a compound of any chemical/structural make-up from any source, including synthetic to selectively inhibit T-cell rolling. The instant specification only teaches and discloses immunotherapeutic compounds comprising purified protein extracts from *Leishmania*; e.g., a purified protein extract wherein said purified extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the *Leishmania* genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex

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and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa. The specification teaches that these compositions can result in the abatement of clinical symptoms of psoriasis. However, the specification has not demonstrated which, if any, of the disclosed compositions can 'interfere' with any or all of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction. There is no correlation or data showing the administration of a disclosed compound and the prevention or inhibition of any of those interactions. It is known in the art that psoriasis is a chronic, remitting and relapsing scaly and inflammatory skin disorder of unknown. It is taught in the art that the mechanism of the human immune system that triggers symptoms of psoriasis consists of T-cell lymphocytes. See Journal of the American Academy of Dermatology, 2003. 49: S44-50. Tables 4-9, 11-14, 22 and Examples 14-17 demonstrate the abatement of symptoms of psoriasis using the composition comprising a purified protein extract wherein said purified extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said

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purified protein extract consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa. However, the specification fails to demonstrate that any one immunotherapeutic agent in the specification specifically interfered with at least one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction. No results are provided which correlate the immunotherapeutic agents and the inhibition or blockage of any of these interactions.

The specification fails to teach or suggest any compounds with the inherent functional properties claimed, with the exception of a purified protein extract wherein said purified extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa which would have the ability to inhibit T-cell rolling through the interference of one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction. The scope of the compounds to be used is extremely broad. Genentech Inc. v. Novo Nordisk A/S (CAFC) 42 USPQ2d 1001 clearly states: "Patent protection is granted in return for an enabling disclosure of an



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invention, not for vague intimations of general ideas that may or may not be workable. See *Brenner v. Manson*, 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." This has not been met in the current specification. The specification has not identified any common structural core which one skilled in the art could use to identify any genus of compounds to be used in the claimed methods. In essence, the applicant is claiming such compounds only by their broad functionality, that of inhibiting T-cell rolling. More than a statement of biological function is required to satisfy the 112 1<sup>st</sup> paragraph enablement requirement.

Accordingly, it would take undue experimentation to make and /or use the invention as claimed.

*Response to Applicants' Arguments:*

Applicants argue that Examples 14 and 15 of the specification demonstrate that the 'claimed agent induces a TH1 response, not humoral immunity or a TH2 response". Applicants' arguments are not commensurate in scope with the claimed invention. First, the claims are not limited to a single claimed agent. They broadly encompass '*any*' agent that inhibits T-cell rolling

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through interference with one of the stated interactions. Examples 14 and 15 use a purified protein extract wherein said purified extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa.

These Examples are insufficient to broadly enable ***any compound from any source possessing any biochemical property*** which inhibits T-cell rolling. It would take undue experimentation on the part of the skilled artisan to identify and test the broad number of possible compounds. The claims are not limited to T-cell rolling caused by any particular disease or infection. Example 14 merely contains ELISA of psoriatic patients before and after vaccination with the protein fractions obtained by isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction derived from isolated killed cells of amastigotes from at least one species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted with a solution comprising 0.1 M. sodium chloride, 8 M urea and 0.025 M. Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract

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consisting of polypeptides having apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa. Example 15 demonstrates an intradermic antigenic reaction in patients after clinical remission of psoriasis. The data indicate that the first-generation immunotherapeutic agent is inducing a TH1 response in cured psoriasis patients. This data is insufficient to enable the extremely broad scope of the claimed invention. The Examples demonstrate that a TH1 immune response may be raised in cured psoriasis patients. They do not demonstrate a method of inhibiting T-cell rolling in **any** human host *caused by any infection or disease through any interference* of a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction.

Applicants also argue that Tables 11-14 indicate that "*the polypeptides of the invention* inhibit lymphoid cell traffice from bood to the skin and from the blood to the synovial membrane". Again, the claims allow for the use of **any** compound and are not limited to any polypeptides, much less the polypeptides "of the invention". Additionally, the Tables do not enable the broadly claimed invention which inhibits any T-cell rolling in a human using any compound that intereferes with CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 1 and 2 are rejected under 35 U.S.C. 102(a) as being anticipated by Pariser, David M. MD. (Managed Care. December 2003. pages 50-56).

NOTE: the instant claims only are entitled to a priority filing date of 2/9/04. The instant claims and methods were first presented in this CIP application and the claimed subject matter was not in the grandparent or parent applications, e.g., inhibiting T-cell rolling by inhibiting CLA and E-Selection, etc..).

Pariser teaches the biology behind T-cell homing (rolling) and how it works in patients with psoriasis (see Figure 1 on page 52 and Figure 3 on page 53, as well as disclosure on pages 52-53). Pariser teaches that instead of solely topical treatments the new biologic agents for treating psoriasis are moving in the direction of systemic therapy. See column 2, page 52. The reference teaches the use of the drug, Efalizumab (RAPTIVA™), to inhibit the LFA-1/ICAM-1 reaction which is used in the prior art for the treatment of psoriasis. See top of column 3, page 52. Instant claims 1 and 2 allow the use of *any* compound which interferes with at least one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VACM interaction. The use of the *Leishmania* compounds described in the specification is not claimed. Efalizumab is an immunostimulant, e.g., a humanized monoclonal antibody.

*Response to Applicants' Arguments:*

Applicants argue that although Pariser describes LFA-1/ICAM interactions, this reference does not describe agents that interfere with CLA-E

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selectin or VLA/VCAM interactions as claimed in claim 1 of the present invention. This has been fully and carefully considered but is not deemed persuasive because claim 1 does not require the compound to interfere with all of the stated interactions just "at least one of the [following] interactions:". Pariser teaches the interference of one of the interactions and, therefore, anticipates the claim. Applicants argue that their invention is drawn to the use of agents that may act through a mechanism of immunostimulation, while Pariser teaches the use of compounds that act as immunosuppressants. This argument is not commensurate in scope with the claimed invention. There is nothing recited in the claims that recites the use of an immunostimulant or negates the use of an immunosuppressant. The claim allows for the "interference" by any means.

8. Prior art made of record:

O'Daly et al (Gac Med Caracas, 103(2): 133-177, 1995). O'Daly et al teach a preparation of a vaccine from Leishmania parasite strains, *L.amazonensis*, *L.venezuelensis*, *L.brasiliensis*, and *L.chagasi*. Each parasite was cultivated and was incubated at the particular temperature of transformation into the amastigote form. Once the parasite reached the amastigote stage they were subjected to a medium with an agent effective to kill the parasites. The parasites were harvested by centrifugation and washed. The isolated parasites were treated by incubation with a medium comprising a detergent, which extracts some proteins from the parasite. The proteins in the total extract were further fractionated and purified by centrifugation. Washing repeatedly further refined the centrifugation pellet comprising fractionated particulate isolated proteins; and,

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the supernatant fraction containing other *Leishmania* proteins was not further used. This centrifugation step is seen as fractionating and purifying the particulate proteins from the detergent extracted proteins and is fact purifying the particulate protein fraction from that solubilized by the detergent medium. The purified/fractionated particulate proteins from the detergent extract were resuspended in medium and then sonicated. The protein content of the extracted sonicate was determined and alumina was added at a concentration of 1mL/mg of protein of each one of the *Leishmania* parasite strains, which were added in equal parts to obtain a final concentration of 1000ug/ml of *Leishmania* antigen. See page 1 of the translation of the article, under "Preparation of vaccine". The process of preparing the *Leishmania* vaccine extract according to O'Daly is substantially the same as that provided for in the specification at pages 3-4 and pages 11-12. Therefore, the composition of a purified protein extract comprising isolated polypeptides that is used in the claimed method appears to be the same as the compositions of the prior art. The proteins contained therein are in fact extracted/isolated/purified from the total amastigote form of the parasite to the same extent as provided for in the extracts of the specification. The recitation of the partial sequences from the *Leishmania* polypeptides found in the composition of the prior art is merely further characterization of the polypeptides of the prior art composition. The sequences are an inherent property of the composition of the prior art.

However, O'Daly does not teach or suggest that the vaccines/compositions can be used in methods to 'selectively inhibit T-cell rolling

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in a human susceptible of psoriasis and that the vaccines/compositions interfere with at least one of the following interactions: a CLA and E-selectin interaction, an LFA-1/ICAM interaction or a VLA/VACM interaction'. Therefore, the reference has not been applied to the current claims.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**.

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

10. Correspondence regarding this application should be directed to Group Art Unit 1645. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Remsen. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is 571-273-8300 which is able to receive transmissions 24 hours/day, 7 days/week.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

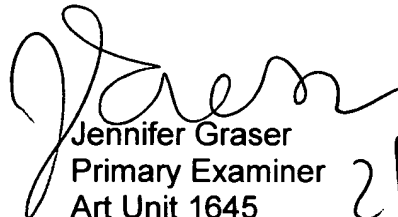
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PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (571) 272-0858. The examiner can normally be reached on Monday-Thursday from 7:30 AM-6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached on (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0500.

  
Jennifer Graser  
Primary Examiner  
Art Unit 1645 2/26/07